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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 08/13/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/555,093	Applicant(s) NAPIER, JOHNATHAN A.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *15-22 and 24-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Response to Restriction Requirement, with traverse, filed on July 8, 2002 as paper No. 13 is acknowledged. Claims 1-38 are pending in the application. Applicants elected Group I, claims 1-3 and 23. Examiner includes Group II, claim 14, to the prosecution. Claims 1-14 and 23 are the subject of this Office Action.

Office Action

1. ***Election/Restriction***

Applicant's election with traverse of Group I, claims 1-13 and 23 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that a search of all invention groups should not present a serous burden. Besides, Applicants argue "if the polynucleotide of Group I is found to be novel, the same polypeptide linked to another moiety also will be novel, as will nucleic acid encoding the polypeptide, methods of making the polypeptide, and the use of the polypeptide to treat disorder."

Applicants' arguments have been fully considered and are found persuasive as to linking of Group I and II, and VIII and IX. Therefore, after linking

Group I claims 1-14, is directed to a polypeptide having desaturase activity, classified 435, subclass 189;

Group VII claims 29-34 and 36-38, is directed to DNA encoding desaturase, expression vector, host and recombinant method of desaturase production, classified in class 435, subclass, 254.21.

Restriction to other groups required in paper No. 12 is found, for reasons presented therein, proper and MADE FINAL. Due to the necessary change in numbering, Groups III-VII are now Groups II-VI, Group VIII is Group VII and Group X is now Group VIII.

Claims 1-14 and 23 belonging to the new Group I are the subject of examination on merits.

2. Objections

The specification has not been checked to the extent necessary to determine the presence of all possible errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may be aware.

3. Rejections

3.1. 35 U.S.C. section 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1-14 and 23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter; Diamond v. Chakrabaty, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein or nucleic acid". It should be noted that a recombinant enzymes/proteins are assumed to be identical to those produced naturally unless otherwise indicated.

3.2. 35 U.S.C. section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-14 and 23 are rejected rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 does not recite the sequence identification number for the sequence to which the claim is directed, i.e., the sequence shown in Fig. 1.

3.3. 35 U.S.C. section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.3.1. Lack of written description

Claims 1-14 and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to a polypeptide having desaturase activity, which:

b) has one or more amino acid deletions, insertions or substitutions relative to SEQ ID NO: 2, but has at least 32% amino acid sequence identity therewith;

c) is a fragment of SEQ ID NO: 2 or polypeptide b) which is at least 100 amino acids long; or

d) is a part o SEQ ID NO: 2 or sequence described in b).

Claims 1-14 and 23 are directed to polypeptide fragments corresponding to portions of the sequence of SEQ ID NO: 2 and variants of SEQ ID NO: 2. Claims 1-14 and 23 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO: 2 including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in SEQ ID NO: 2 and fragments of SEQ ID NO: 2 that have not been disclosed in the specification. No description has been provided of the modified polypeptide sequences encompassed by the claim. Examiner noted that the sequence listing contains in addition to polypeptide of SEQ ID NO: 2, polypeptides identified by SEQ ID NO: 4, 5, and 7, all coming from C. elegans; no information, however, beyond the characterization of SEQ ID NO: 2 has been provided by applicants which would indicate that they had possession of the claimed genus of modified polypeptides. The

genus of polypeptides claimed is a large variable genus. The specification discloses only a single species of the claimed genus, SEQ ID NO: 2, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that applicant had possession of the claimed invention at the time the instant application was filed.

3.3.2. Scope of enablement

Claims 1-14 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for *C.elegans* desaturase Δ^6, does not reasonably provide enablement for any polypeptide having desaturase activity, when said polypeptide

b) has one or more amino acid deletions, insertions or substitutions relative to SEQ ID NO: 2, but has at least 32% amino acid sequence identity therewith;

c) is a fragment of SEQ ID NO: 2 or polipeptide b) which is at least 100 amino acids long; or

d) is a part o SEQ ID NO: 2 or sequence described in b).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are directed to any desaturase, its variants having at least 32% identity and fragments having desaturase activity. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of proteins and their properties broadly encompassed by the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)), otherwise undue experimentation is necessary.

Factors to be considered in determining whether undue experimentation is required to make the claimed invention are summarized *In re* Wands [858 F.2d 731, 8

USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses any desaturase from any source, or man made, that has at least 32% identity to SEQ ID NO: 2, or is a fragment or at least 100 amino acid fragment of SEQ ID, or is a fragment of at least 100 amino acid fragment of the polypeptide that is at least 32% identical to SEQ ID NO: 2.

Although the methods of gene cloning and manipulation are well developed and skills of artisans are high, it is not a routine in the art to clone all possible desaturases from all natural or man made sources and select those that are at least 32% identical to SEQ ID NO: 2. Also, it is not a routine experimentation in the art to modify SEQ ID NO:2 by making deletions, insertions and substitutions resulting in a protein that has 32% identity to SEQ ID NO:2 and desaturase activity. It is not possible to select all at least 100 amino acid fragments of such desaturases that retain the desaturase activity and any parts of such desaturases that retain desaturase activity. Probability of success in making the invention is very low.

The specification does not support the broad scope of the claims. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The examiner finds that one skilled in the art would require additional guidance, regarding to which desaturase protein of many known, and from which organism, to choose, as well as what are the rules for performing substitutions, deletions or insertions without an adverse effect on the protein function. Without such guidance, the experimentation left to those skilled in the art is undue.

3.4. 35 U.S.C., section 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipate by US Patent No. 5,098,809, granted to Knutzon et al., on Oct. 19, 1999, with filing date April 11, 1997.

Claim 1, part b) is directed to a polypeptide having desaturase activity, wherein the polypeptide is at least 32% identical to SEQ ID NO:2.

Knutzon et al disclose desaturase Δ^6 from *Mortierella alpina,* having the amino acid sequence that is in 32.1% identical to SEQ ID NO: 2 of the instant application. See the attached alignment.

4. Allowable subject matter

No claim is in condition for allowance. However, the claims contain the allowable subject matter. The following is examiner's reason for allowable subject matter.

Applicants cloned the desaturase Δ^6 gene from *C. elegans* and disclosed for the first time the encoded protein had the desaturase Δ^6 activity. The enzyme has an industrial application in production of γ-linoleic acid useful in treatment of a number of medical conditions, including eczema and mastalgia.

The closest prior art relates to the *C. elegans* predicted protein WO8D2.4 (Swineburne J. and Ainscough R. March 23, 1996, enclosed in the Information Disclosure Statement); see alignment of WO8D2.4 protein and SEQ ID: 2 in Fig. 2B of the application. The sequences of WO8D2.4 and SEQ ID NO: 2 are not the same and the function of the protein was unknown at the time its gene was discovered by

Swinburne and Ainscough. The WO8D2.4 protein was described as transporter ATPase like, tyrosine–protein kinase, human myeloid cell line protein like and collagen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner

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